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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/080,532	02/22/2002	Malcolm L. Gefter	PPI-107	8658

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EXAMINER	
LEFFERS JR, GERALD G	

ART UNIT	PAPER NUMBER
1636	

DATE MAILED: 06/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/080,532	GEFTER, MALCOLM L.	
	Examiner	Art Unit	
	Gerald G Leffers Jr., PhD	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 February 2002*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-63* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-63* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-63 are pending in the instant application and are subject to the following restriction requirement. The following restriction requirement comprises 18 different and distinct groups of inventions for reasons that are outlined below. This is not a species election requirement.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I-VII. Claims 2-30 are drawn to a method of identifying a peptide that modulates a biological process comprising directly contacting cells with a peptide library, classified in class 435, subclasses 4 and 29. Each of Groups I-VII is directed to a distinct biological process that is assayed for modulation (i.e. apoptosis, protein trafficking, cell adhesion, membrane transport, cell motility, cell differentiation and progression of a disease state, respectively).

VIII-XIV. Claims 2-30 and 32-45 are drawn to a method of identifying a peptide that modulates a biological process comprising expressing a peptide library in transfected host cells, classified in class 435, subclasses 6, 69.1. Each of Groups VIII-XIV is directed to a distinct biological process that is assayed for modulation (i.e. apoptosis, protein trafficking, cell adhesion, membrane transport, cell motility, cell differentiation and progression of a disease state, respectively).

XV. Claims 46-56 are drawn to methods of identifying a polypeptide that modulates the infectivity of a pathogenic organism, classified in class 435, subclasses 6, 69.1 and 29.

XVI. Claims 57, 59 and 63 are drawn to peptides, pharmaceutical compositions and kits comprising the peptides, classified in class 530, subclasses 300 and 350.

XVII. Claim 58 drawn to a method of using an isolated peptide for molecular modeling, classified in class 435, subclass 4.

XVIII. Claims 60-62 are drawn to methods of treatment using a peptide composition, classified in class 514, subclass 2.

The inventions are distinct, each from the other because of the following reasons:

Claim 1 link(s) inventions within Groups I-VII with regard to the nature of the biological process that is assayed/modulated. Likewise, claims 1 & 31 link inventions with Groups VIII-XIV with regard to the nature of the biological process that is assayed/modulated. Finally, claim 1 links the inventions of Groups I-XIV with regard to the manner in which the target cells are contacted with the peptide library (i.e. direct contact with isolated peptides or via an expression library). The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s), claims 1 and 31. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking

claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Inventions of Groups I-VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). Within Groups I-VII, each group is directed to a distinct method where a different biological process is modulated and for which a different method of assaying for such modulation is required. As each of the biological processes has different etiology and effects on a given cell/tissue/organism, each requires distinct methods steps having a different outcome based upon the type of process that is monitored (i.e. apoptosis, protein trafficking, cell adhesion, membrane transport, cell motility, cell differentiation and progression of a disease state, respectively). Therefore, each of the different Groups is directed to a method having different modes of operation, functions and effects from the methods of the other groups.

Inventions of Groups VIII-XIV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). Within Groups VIII-XIV, each group is directed to a distinct method where a different biological process is modulated and for which a different method of assaying for such modulation is required. As each of the biological processes has different etiology and effects on a given

cell/tissue/organism, each requires distinct methods steps having a different outcome based upon the type of process that is monitored (i.e. apoptosis, protein trafficking, cell adhesion, membrane transport, cell motility, cell differentiation and progression of a disease state, respectively). Therefore, each of the different Groups is directed to a method having different modes of operation, functions and effects from the methods of the other groups.

Inventions of Groups I-VII and Groups VIII-XIV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have methods steps that are not required for the methods of the other groups: directly contacting cells with a peptide library (Groups I-VII) and expressing a library of expression vectors in host cells (Groups VIII-XIV). Thus, the mode of operation, effects and functions of the different methods of the different groups are different. Therefore, the inventions of Groups I-VII and Groups VIII-XIV are capable of supporting separate patents.

Inventions of Group XV and Groups I-XIV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation, different functions and different effects. For example, the methods of Group XV comprise steps that are not present in or required for the methods of Groups I-XIV (e.g. contacting the target host cell(s) with a pathogenic organism) and which result in a distinct outcome (i.e. identification of a peptide that modulates the infectivity of a pathogenic organism).

Inventions of Group XVI and Groups I-XV & XVII-XVIII are related as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the isolated peptides of Group XVI can be used in any of the processes of Groups I-VII, XVII and XVIII. Alternatively, the peptides can be used to generate antisera against the specific peptide. Further, the peptides of Group XVI can be identified by other methods and do not require the methods of Groups I-XV & XVII-XVIII for their production (e.g. the peptides can be obtained from nature and/or obtained synthetically).

Inventions of Group XVII and Groups I-XV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different methods of Groups I-XV comprises methods steps that are not required for or present in the methods of Group XVII, and vice versa: contacting target cells directly or indirectly with a peptide and observing the effect on a biological process (Groups I-XV) and molecular modeling of a compound (Group XVII). The methods of the different groups have different end results: identification of a peptide that modulates a given biological process in group of target host cells (Groups I-XIV), identification of a peptide that modulates infectivity of a pathogen (Group XV) and identification of a compound that has similar binding characteristics of a peptide that modulates a given biological process in particular host cells (Group XVII).

Therefore, the methods of the different and distinct groups are capable of supporting separate patents.

Inventions of Group XVIII and Groups I-XV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different methods of Groups I-XV comprises methods steps that are not required for or present in the methods of Group XVIII, and vice versa: contacting target cells directly or indirectly with a peptide and observing the effect on a biological process (Groups I-XV) and administering to a subject a peptide (Group XVIII). The methods of the different groups have different end results: identification of a peptide that modulates a given biological process in group of target host cells (Groups I-XIV), identification of a peptide that modulates infectivity of a pathogen (Group XV) and treatment of a disease or condition (Group VIII). Therefore, the methods of the different and distinct groups are capable of supporting separate patents.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper. Further, for those embodiments having similar classification, the nonpatent literature search for each of the different groups is different (e.g. identification of peptides vs. similar methods further comprising contacting target cells with a pathogen and assaying infectivity).

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gerald G Leffers Jr., PhD whose telephone number is (571) 272-0772. The examiner can normally be reached on 9:30am-6:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Gerald G Leffers Jr., PhD
Primary Examiner
Art Unit 1636

GERRY LEFFERS
PRIMARY EXAMINER